IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES, LLC, Plaintiffs, v. COREVALVE, INC., and MEDTRONIC COREVALVE, LLC, Defendants.	C.A. No. 08-091 (GMS) REDACTED - PUBLIC VERSION

DEFENDANTS' ANSWERING BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR PERMANENT INJUNCTION

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Dated: July 26, 2010
Redacted Version: August 2, 2010

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I. NATURE AND STAGE OF THE PROCEEDINGS

Following the Court's entry of judgment on May 4, 2010, defendants CoreValve, Inc. and Medtronic CoreValve LLC ("CoreValve") renewed their motions for JMOL and for a new trial. D.I. 335, 336. Should the Court overturn the finding of liability for any reason, plaintiff Edwards Lifesciences LLC and Edwards Lifesciences AG's ("Edwards") motion for an injunction would be moot.

Relying on the verdict, this motion seeks to disrupt to the greatest extent possible the supply of CoreValve transcatheter heart valves ("THV") to doctors and patients around the world. And yet Edwards offers very little evidence that it would be any better off with an injunction. This is because CoreValve is entitled to sell its THV in Europe and elsewhere outside the United States, where it prevailed against Edwards' infringement claims. Neither company has FDA approval to sell in the United States, and CoreValve will not have such approval before the '552 patent expires in 2012. At stake in this motion are two interests: (1) U.S. manufacturing jobs that would need to be eliminated to comply with Edwards' injunction, and (2)

Neither consequence of an injunction serves Edwards', the patent system's or the public's interest. To the extent Edwards also seeks to have the injunction apply for some unspecified and unknown *extended* term of the '552 patent, the stakes are even higher, for then Edwards directly seeks to deny treatment options to patients in the United States. CoreValve hereby opposes Edwards' motion.

II. SUMMARY OF ARGUMENT

If there is one thing the parties agree on in this case, it is that both CoreValve's Gen 3 and Edwards' Sapien devices save lives. Thus, the fundamental question in this motion is whether an

injunction that threatens to disrupt the supply of life-saving CoreValve devices to needy patients is warranted. CoreValve submits it is not.

1. Injunctive relief is an extraordinary remedy that must be supported with substantial evidence. Edwards has not provided such evidence.

2.

. If the assumption holds true, it closes the door on any showing of irreparable harm since the level of competition Edwards would face would be identical with or without an injunction.

3. If the assumption does not hold true, even modestly, patients will bear the cost without any clear benefit to Edwards. Edwards offers no evidence it will lose customers or market share barring an injunction. The sole act of infringement—manufacturing in the United States—poses no prospective harm to Edwards different from what it would experience if CoreValve manufactured outside the United States. And Edwards has not shown why damages would not adequately compensate it, particularly in light of its own licensing history and its proposal in this motion for a partial compulsory license.

4. Regarding relative hardships, Edwards has offered no evidence as to how it would be any differently situated if CoreValve is forced to manufacture outside the United States. CoreValve, however, would face severe disruption of its U.S. operations.

5. The public interest weighs heavily in this case.

CoreValve is the only device suitable

for several categories of patients. Edwards concedes that the risk to patients if CoreValve were enjoined warrants a compulsory license for one category of patients not treatable with Sapien, but many other categories of patients would still be at risk under Edwards' proposed injunction. Lastly, if the injunction had no effect on supply of devices to patients, the net result would be nothing more than the loss of many quality domestic manufacturing jobs to Mexico. Such an outcome is not in the public interest.

6. Edwards appears to seek an injunction beyond the natural life of the '552 patent without having even sought an extension from the PTO, much less received it. Edwards makes no showing as to any *eBay* factor for this hypothetical extended term, and in particular does not justify potentially denying United States patients access to the best available medical treatment. Any injunction should be limited to the natural life of the '552 patent.

7. Edwards also seeks by this injunction to reach CoreValve's Mexican operations under 35 U.S.C. § 271(f). Edwards has argued that issues surrounding Mexico production are part of a second lawsuit before this same Court. Any injunction should exclude Section 271(f) language.

III. STATEMENT OF FACTS

A. Many physicians prefer CoreValve's Gen 3 because of its ease of use and the broad patient profile it can serve.

Over 300 physicians around the world have chosen CoreValve as the THV best-suited for their patients. A415 at ¶ 2. Of those certified CoreValve physicians, about 25% are also certified on Edwards' Sapien. *Id.* And these dual-user doctors use CoreValve's device over three times more frequently than Sapien. A88; *see also* A419 at ¶ 11; A422 at ¶ 5.

CoreValve presents the sworn statements of five doctors on three continents who uniformly view CoreValve as essential to their practice. For the following categories of patients, the CoreValve THV is the only viable treatment option:

- Patients with an aortic annulus larger than 25 mm, which is estimated to be at least 15% of the population. D.I. 328 at 564:17-24; A 338 (noting as many as 45% of patients have a 25 mm or greater annulus).
- Patients whose coronary arteries are less than 1.5 mm from their native aortic valve, because in such patients the Sapien raises too great a risk of a debilitating blockage of the coronary arteries. A666 at ¶ 9; A426-427 at ¶ 10.
- Patients who have a discrete upper septal bulge in the heart, because the condition interferes with proper placement of the Sapien valve by balloon expansion, but does not affect CoreValve placement. A423 at ¶ 9.
- Patients with a bicuspid (as opposed to the normal tri-cuspid) aortic valve. A422-A423 at ¶8
- Patients suffering from aortic regurgitation (valve leakage into the ventricle) who often have an aortic annulus too large for Sapien. A423 at ¶ 10.
- Patients who cannot be treated transfemorally or transapically with Sapien, but for whom skilled physicians can use a "subclavian" technique to implant the CoreValve THV. A418 at ¶ 7; A426 at ¶ 8.

Without the CoreValve device, these patients would face a grim prognosis. A portion of them would not live more than several months without treatment. A429 at ¶ 6 (14% of patients die between referral and actual procedure, which is typically about four months); A423-A424 at ¶12.

It is for these reasons that the literature recommends that both devices be available to physicians for optimal patient treatment. A353-A354.

Even for a patient who fits within the profile for Sapien use, many doctors find the CoreValve THV the better solution. An important advantage doctors value is the ability to reposition the CoreValve THV even after it is partially deployed. A422 at ¶ 7; A419 at ¶ 10; A666 at ¶ 8. For a procedure that requires precise placement of the device in the very turbulent environment of the left ventricle/aortic valve/ascending aorta, this feature is critical, and has been used repeatedly. *Id.*; *see also* D.I. 330 at 1106:1-23.

The CoreValve THV is available to a broader group of doctors, and therefore more potential patients, because it is used truly percutaneously. That is, it can be implanted with only a small puncture wound and typically without surgical or general anesthesia support. This means that doctors can offer THV treatment even in medical centers where surgical resources are scarce or unavailable. D.I. 330 at 1108:21-1110:12. On the other hand, because Sapien is used transapically 50% or more of the time, Sapien centers require costly surgical backup support. A373 at 60:5-6 (two-thirds of Sapien sales are for transapical use); A429-A430 ¶ 8; A666 at ¶ 7.

Finally, as the devices are used more and more, doctors are observing different consequences or complications. For example, literature from 2010 suggests that Sapien's balloon expandable design is associated with a significantly higher rate of kidney (renal) failure than the self-expanding CoreValve. A344 at 2177, Table 2 (58% versus 17%); A349 (45% versus 17%). For all these reasons, physicians believe that disrupting the supply of CoreValve devices will have grave consequences for the unfortunate patients in line for treatment.

B. To protect doctors, and their patients, who rely upon a supply of CoreValve THVs, Medtronic has made plans for alternative manufacture in Mexico.

CoreValve has undertaken steps to ensure that its Gen 3 THV will be available to doctors by setting up alternative manufacturing facilities in Mexico.

IV. ARGUMENT

A. The *eBay* factors do not support an injunction through the natural term of the '552 patent.

A permanent injunction is "a drastic and extraordinary remedy," and "[i]f a less drastic remedy . . . [is] sufficient to redress [plaintiffs'] injury, no recourse to . . . an injunction [is] warranted." *Monsanto Co. v. Geertson Seed Forms*, __U.S.__, 130 S.Ct. 2743, 2748 (2010). In order to obtain a permanent injunction, the burden is squarely on Edwards to demonstrate: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExhange, L.L.C.*, 547 U.S. 388, 391 (2006). Edwards has not met its burden as to any of these requirements.

1. Edwards will suffer no irreparable harm if its motion fails.

Edwards must prove that it is entitled to an injunction by citing specific facts showing irreparable injury and the inadequacy of legal remedies. *Praxair, Inc. v. ATMI, Inc.*, 479 F. Supp. 2d 440, 443 (D. Del. 2007). No presumption of irreparable harm attaches to a finding of infringement, even in a two-supplier market. *eBay*, 547 U.S. at 393; *Praxair,* 479 F. Supp. 2d at 443-4 (declining to grant injunction where parties were in "direct and head-to-head competition" because plaintiff failed to provide "any specific sales or market data").

Edwards' failure to cite any prospective lost customers or other evidence of prospective irreparable harm alone defeats this motion. *Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 559 (D. Del. 2008) (no irreparable injury where patentee "has not identified any specific customers it has lost, or stands to lose, directly as a result of [plaintiff's] continued [infringement]");[1] *see also, IMX, Inc. v. LendingTree, LLC*, 469 F. Supp. 2d 203, 226 (D. Del. 2007) (declining to grant injunction "[a]bsent any specific information regarding the effect of defendant's infringing operation ... on plaintiff's business").

The evidence of record actually calls into doubt whether Edwards would benefit from any fewer CoreValve THVs on the market over the next twenty-two months.

[1] Edwards should not be permitted to use its reply papers to attempt to correct for its failure of evidence, especially in light of Edwards' refusal to participate in any meaningful discovery in advance of the briefing for this motion. D. Del. LR 7.1.3(c)(2); *see* A376-A407.

At the time of trial, Edwards had a "big unmet patient need," and Edwards always had a list of centers waiting to be trained. D.I. 328 at 585:23-589:14.

See D.I. 357 at 15.

Voda v. Cordis, Corp., 536 F.3d 1311, 1329 (Fed. Cir. 2008) (declining to grant permanent injunction where plaintiff failed to "identif[y] any irreparable injury to himself due to [the defendant's] infringements of [its] patents").

Also, since CoreValve does not have FDA approval to sell commercial product in the U.S. before the May 2012 expiration date, an injunction would only affect manufacturing, not sales. Edwards must show that CoreValve's U.S. *manufacturing* causes irreparable harm. But it has offered no evidence in this regard. And, Edwards' claim that certain press reports "compromised" Edwards' reputation (D.I. 357 at 9) is irrelevant since CoreValve's devices can and will be legally promoted and sold outside the U.S., where Edwards' infringement claims were repeatedly rejected. *See* A248-A334. Edwards simply fails to link any irreparable harm to manufacturing, which is the sole act of infringement.

Edwards' evidence of past lost market share does not suffice either. Past events *can* be relevant to assessing future irreparable harm, but only when they suggest that future harm is not compensable by a monetary award. Thus, in *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 861 (Fed. Cir. 2010), the infringement resulted in total obsolescence of the plaintiff's product and forced a change in plaintiff's business model. Here, Edwards' cites the "first-mover

advantage" CoreValve allegedly enjoyed several years ago. D.I. 357 at 12. Even if it existed, this "advantage" occurred only when CoreValve "first moved" into the market, and so by definition, it cannot be repeated in the future. *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1334, 1347-48 (Fed. Cir. 2006) (denying injunction because "irreversible market share losses" "does not establish that [plaintiff's] harm will be irreparable"). Edwards' and CoreValve's respective market shares are well-established, A415-A416 at ¶ 3, so any harm flowing from ongoing CoreValve conduct would be easily calculable. *IGT v. Bally Gaming Intern. Inc.*, 675 F. Supp. 2d 487, 492-93 (D. Del. 2009) ("While it is true that history cannot now be rewritten to remove [defendant] from the field of competition during a growth period ... on the record at bar, defendants' sales ... appear to be quantifiable.").

The glaring lack of evidence of irreparable harm may explain why Edwards never even sought a preliminary injunction earlier in this case. *See MercExchange, L.L.C. v. eBay, Inc.*, 500 F. Supp. 2d 556, 573 (E.D.Va. 2007) (failure to seek preliminary injunction was a "factor in the calculus" indicating no irreparable harm). Edwards was correct then not to seek an injunction, and cannot show irreparable harm even now.

2. Money damages are adequate to compensate for CoreValve's alleged infringement

Edwards does not cite a single piece of evidence regarding this factor. No injunction should issue where the plaintiff cannot "iterate specific reasons why the infringement cannot be compensated for with a money award." *Praxair*, 479 F. Supp. 2d at 444.

"Engaging in licensing activity is incompatible with the right to exclude" and indicates that any future injury would be compensable with money damages. *Telecordia Techs., Inc. v. Cisco Systems, Inc.*, 592 F. Supp. 2d 727, 748 (D. Del. 2009), *aff'd in pertinent part*, Nos. 2009-1175, 2009-1184, 2010 WL 2653251 (Fed. Cir. July 6, 2010). Edwards licensed the '552 patent

at a 4% royalty rate to a competitor, 3F Therapeutics, for a field of use that includes transapical delivery. A116. Transapical usage is as much as two-thirds of Edwards' Sapien usage. A373 at 60:5-6.[2] Since Edwards has agreed to monetary compensation for competition with such a large portion of its business, it cannot complain now that monetary damages are inadequate.

In addition to the 3F license, Edwards concedes that a compulsory license is adequate for some of CoreValve's ongoing acts. The "carve out" Edwards proposes in its injunction (D.I. 356, proposed order at 3) implicitly concedes that a license payment is adequate compensation at least for any device used in a patient that Sapien cannot serve. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs.*, No. CV-03-0597, 2009 WL 920300 (D. Ariz. Mar. 31, 2009) (awarding a compulsory license instead of an injunction). As explained above at 4-5, however, Sapien is not a viable option for many more categories of patients than just those patients with a large aortic annulus. Additionally, many doctors and medical centers are not able to support the resource demands of Sapien. Rather than attempt to fashion "carve outs" that accommodate all such patients and doctors, the more judicious course is to deny injunctive relief.

3. The balance of hardships weighs against an injunction

As explained above, Edwards offers no evidence to advance its claim of irreparable harm. If Edwards' assumption is true—

—then regardless of whether an injunction issues, Edwards will continue to face the same degree of competition from CoreValve in the markets where its product can be sold. As a result, Edwards faces no hardship.

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[2] Edwards cannot distinguish this license based on the difference between transfemoral THV delivery since it has repeatedly claimed they are equivalent. *See, e.g.*, D.I. 357 at 5. Moreover, "[t]he fact that [the patentee] was selective regarding its licensing ... does not rectify the fact that [Edwards] was willing, ultimately, to forego its exclusive rights ... for compensation." *Advanced Cardiovascular Sys.*, 579 F. Supp. 2d at 560.

A431-A432 at ¶¶ 3, 5.

. A432 at ¶ 5. .

See A416 at ¶ 6. Such hardship weighs against an injunction. *Datascope Corp. v. Konton, Inc.*, 611 F. Supp. 889, 895 (D. Mass 1985) (denying injunction because defendant made strong showing that it will suffer losses in sales, it will be forced to lay off employees, and its goodwill will be injured).

4. The public would be disserved by a permanent injunction against CoreValve's unique life-saving device.

"In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982). The public interest weighs heavily against an injunction in this case.

. *See, e.g., Cordis Corp. v. Boston Scientific Corp.*, Nos. Civ. A. 03-027, 03-283, 2003 WL 22843072 at *2 (D. Del. Nov. 21, 2003) (denying preliminary injunction in part because "it is apparent from the evidence that Cordis cannot ensure an adequate supply of drug-eluting stents to meet current market demand"); *see also E. I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277, 278 (Fed. Cir. 1987) (staying injunction pending appeal where defendant asserted there would otherwise be "a

severe and immediate shortage in the polyethylene market...and that users will be unable to find supplies").

The public interest also favors maintaining options for consumers, and avoiding a single-supplier market for life-saving products. *See Bard*, 2009 WL 920300 at *9 (denying permanent injunction because "Placing [the defendant's] infringing products out of reach of the surgeons who rely on them would only work to deny many sick patients a full range of clinically effective and potentially life saving treatments."). In *Advanced Cardiovascular Sys.* the court denied injunctive relief because of the "strong public interest in maintaining diversity in the coronary

[3] In addition, even if Edwards could retrain some physicians, the level of care would still suffer due to a "learning curve" associated with the new device. *See* A429 at ¶ 7.

stent market" and "evidence of physician preference for [the defendant's] stents." 579 F. Supp. 2d 554, 561 (D. Del. 2008) (citing *Cordis Corp. v. Boston Sci. Corp.*, 99 Fed. Appx. 928, 935 (Fed. Cir. 2004) (unpublished) ("[A] strong public interest supports a broad choice of drug eluting stents, even though no published study proves the superiority of either...stent.")).

For many patients, CoreValve is the *only* THV treatment available, and without it "some nontrivial number of patients would not be able to receive the treatment their physician preferred." *Kimberly-Clark Worldwide, Inc. v. Tyco Healthcare Group LP*, 635 F. Supp. 2d 870, 882 (E.D. Wis. 2009).

- Sapien cannot treat the significant percentage of patients with annulus sizes larger than 25 mm. D.I. 328 at 564:17-24; A338 (noting as many as 45% of patients have a 25 mm or greater annulus).
- Sapien cannot be used to treat patients with a bulging septum or a bicuspid aortic valve. A422-A423 ¶¶ 8-9; A420 at ¶ 14.
- Sapien is dangerous for patients with coronary ostia less than 1.5 mm from the native aortic valve. A666 at ¶ 9; A426-A427 at ¶ 10.

For certain patients femoral access is impossible even with Sapien XT or CoreValve. Doctors have treated these patients using CoreValve in a "subclavian" technique: a minimally invasive procedure that requires no surgical support or general anesthesia. A351; A340; A418 at ¶ 7. If only Sapien were available, however, these patients' only option would be a "far more invasive" transapical technique, which entails "considerably more pain and discomfort," requires a "longer and more painful recovery," and poses "a risk for far more severe complications." A418-419 ¶¶ 8-9. A353-A354; A364. Many patients are not suited for this high impact procedure at all, and without CoreValve would be deprived of THV treatment. A422 at ¶ 6.

And some medical centers cannot support the resource demands of transapical procedures. A429-A430 ¶ 8; A666 at ¶ 7; D.I. 330 at 1108:21-1109:25.

The solution to these threats to patient well-being is not Edwards' overly narrow "carve out" in its proposed injunction; it is to deny injunctive relief. Courts rightly "avoid getting in the way of a fluid and broad-based approach to solving the [medical] problems" such as aortic valve replacement. *Kimberly-Clark Worldwide,* 635 F. Supp. 2d at 882; *see also Bard*, 2009 WL 920300 at *7 (denying injunctive relief where doctor declared that removal of defendant's product from market "would expose my patients to more risk of complications"). Clinics and physicians trained on both devices have chosen CoreValve almost three times as often as they have used Sapien. A88; A422 at ¶ 5. Physicians also prefer CoreValve's THV because it can be repositioned after placement, or even retracted back into the delivery catheter. *See* A422 at ¶ 7; A419 at ¶ 10; see also A370.

Unfortunately, Edwards has resisted any updates on discovery regarding concerns physicians or others have expressed about Sapien. But even from the public domain, it is clear even there are issues with Sapien. Proctors for Edwards documented the higher rate of acute renal failure in patients receiving balloon expandable devices (*i.e.*, Sapien) as opposed to self-expanding devices (CoreValve). A344, Table 2 (58% versus 17%); A349 (45% versus 17%). Also, Edwards has issued at least two Field Safety Notices in 2010 about potential problems using Sapien. A408-A414. We may not know for some time how many other, or perhaps more serious, issues exist regarding Sapien. In all events, the lack of evidence regarding Sapien must be held against Edwards. *See Kimberly-Clark*, 635 F. Supp. 2d at 882 (holding that "in the absence of any evidence from [the plaintiff] that [the defendant's] products fail to offer any

advantage, it is difficult to find that [the plaintiff] has met its burden on the public interest question").

Finally, Edwards contends that injunctions serve the public's interest in enforcing patent rights. "[A]lthough that argument has some superficial appeal, accepting it at face value would render much of the four-part injunction analysis unnecessary." *Kimberly Clark*, 635 F. Supp. 2d at 881. Enforcing patent rights in this case in the way Edwards requests would have the perverse effect of driving jobs, and tax revenue, out of the United States and into Mexico without any corresponding benefit to Edwards. *See, e.g., American Cyanamid Co. v. U.S. Surgical Corp.*, 833 F. Supp. 92, 133-34 (D. Conn. 1992) (concluding that injunction that would "force [the defendant] to lay off many employees" would "not serve the public interest"). Here, under any fact scenario, the public interest strongly favors denying the injunction request.

5. If the Court is inclined to grant an injunction, CoreValve requests that the Court stay it pending appeal.

Even if the public interest evidence does not persuade the Court to deny injunctive relief outright, CoreValve submits that it supports a stay of any injunction pending appeal. Where there is doubt about a patentee's ability to satisfy an important public demand for a product, a stay with a posting of security can be the appropriate remedy. *Advanced Med. Optics, Inc. v. Alcon Labs., Inc.*, No. 03-1095-KAS, 2005 WL 3454283 (D. Del. Dec. 16, 2005). For all the reasons described above, CoreValve requests a stay pending appeal[4].

[4] Furthermore, the very strong non-infringement arguments concerning the "projecting" and "generally parallel" claim elements set forth in CoreValve's Renewed JMOL papers (D.I. 335 at 3), counsel in favor of a stay so as not to jeopardize patients' lives while the verdict is on appeal.

B. Should an injunction issue, it should not grant Edwards excessive rights to disrupt patient access to CoreValve's lawful business.

1. There is no basis for an injunction that extends beyond the natural term of the '552 patent, ending May 2, 2012.

By way of footnote 4, Edwards suggests its injunction may extend far beyond the May 2, 2012 natural expiration date of the '552 patent, even though Edwards has neither applied for nor been awarded an extension beyond the May 2, 2012 expiration date. Edwards may not seek an injunction to prevent others from encroaching on rights that it has not yet obtained. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 101, 109-110 (1983) (plaintiff lacked standing to obtain injunctive relief because his injury was speculative). Its request for injunctive relief based on events that have not yet taken place is not ripe for adjudication. *See National Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803 (2003). Granting Edwards an injunction for an extended term would be the equivalent of enjoining a defendant from trespassing before the plaintiff purchased the property. *See eBay, Inc.*, 547 U.S. at 392 ("[T]he Patent Act itself indicates that patents shall have the attributes of personal property").

The Court need not decide now if Edwards is entitled to an injunction for an extended term. First, Edwards might not even apply for an extension on the '552 patent, choosing instead a different patent to attempt to protect its Sapien product. *See* 35 U.S.C. § 156; *Cardiac Pacemakers v. St. Jude Med.*, No. 96-1718-C-H/G, 2001 WL 483973, *9 (S.D. Ind. May 2, 2001) (the Act allows "one patent extension per patent, one patent extension per product, and one product per patent extension").

Second, Edwards may not get the extension. To obtain an extension, the patent has to "claim" the product to be protected. 35 U.S.C. § 156. "Claims" under Section 156 does not mean the same as "infringement." *Hoechst-Roussel Pharm, Inc. v. Lehman* 109 F.3d 756, 759 (Fed. Cir. 1997). There is no basis to assume that the '552 patent "claims" the Sapien device.

Third, any extension may not support an injunction against CoreValve. The extension restores the patentee's rights only for the *product* that is the basis of the application, not the full scope of the claim. *Merck & Co. v. Kessler*, 80 F.3d at 1547 (Fed. Cir. 1996); 35 U.S.C. § 156(b)(1). The patent owner's right to exclude others from practicing the full scope of the claim ends on the original expiration date of the patent. *Id.* An extended term would not necessarily affect CoreValve.

Even if the extended term were a certainty, Edwards has not met its burden of proof to obtain an injunction for that term. Edwards must demonstrate that it is entitled to the full scope of the requested injunction, including any extension. *See Salazar v. Buono*, 130 S.Ct. 1803, 1816 (2010) (injunctive relief must consider significant changes in "future course of events"); *TruePosition Inc. v. Andrew Corp.*, 568 F. Supp. 2d 500, 534 n. 48 (D. Del. 2008) ("A plaintiff must forward sufficient proof of market competition and/or market harm vis-à-vis the broad scope of the relief requested"). Edwards made no such showing as to the future market conditions. It even contended such information was irrelevant in order to resist any discovery. *See* A381, A386 (Edwards's Response to CoreValve's RFP 2, 12). That market will likely look very different in 2012.[5] For all these reasons any injunction should be limited to the natural life of the '552 patent, and if and when Edwards receives an extension it can petition the Court for relief.

2. Should an injunction issue, it should not disrupt CoreValve's Mexico operations.

Edwards should not be able to obtain by way of injunction in this case relief for conduct it claims is in dispute in another case. In a recently filed brief in another case before this Court,

[5] By 2012, many new competitors are expected to enter the market, including St. Jude and Cordis. See A483-A484, A602. Several of these companies—Sadra-Lotus, Hansen Medical, Sorin Perceval, ATS 3f enable, and JenaValve—have started clinical studies on their devices. A437, A609-A661.

Edwards asserted that the activities surrounding CoreValve's plan to move manufacturing to Mexico were *not* adjudicated in this case, but are rather part of the new case, *Edwards Lifesciences AG v. Medtronic, Inc.*, 09-873-GMS ("*Edwards II*"). *Edwards II*, D.I. 18, at 8-9, 17-18. CoreValve agrees. Edwards' effort to enjoin those activities in this motion, under the guise of §271(f) (D.I. 356; *Edwards II*, D.I. 18, at 17 n.5) is improper because Edwards did not attempt to raise those issues in this case.[6] *Extreme Networks, Inc. v. Enterasys Networks, Inc.*, No. 07-229, at *4-5 (W.D. Wis. Oct. 29, 2008) (patentee was not entitled to permanent injunction based on claim it chose not to assert and that was not adjudicated); *see also Gemveto Jewelry Co. v. Jeff Cooper Inc.*, 800 F.2d 256, 259 (Fed. Cir. 1986) ("[I]njunctive relief should be narrowly tailored to fit the specific legal violations."). Indeed, should Edwards prevail in its opposition to CoreValve's stay motion in *Edwards II*, Edwards would be judicially estopped from denying that its 35 U.S.C. § 271(f) claims concerning Mexico are the subject of *Edwards II*. *In re Teleglobe Commc'ns Corp.*, 493 F.3d 345, 377 (3d Cir. 2007).[7] Edwards has made these activities the subject of a new case, and while CoreValve is confident they do not amount to infringement, it should be entitled to a full hearing before its product supply is further disrupted.

Should the Court consider granting Edwards the § 271(f) language it requests, CoreValve respectfully requests confirmation that

[6] Edwards was fully aware of CoreValve's Mexico plans no later than February 2010, well before trial started in this case. It made a tactical decision not to assert claims regarding Mexico in this case. *See, e.g.*, *Edwards II*, D.I. 20, ex. A at 82:7-9. Also this Court explicitly found Edwards could have raised, but had failed to raise, other § 271(f) issues. D.I. 280, at 5-6.

[7] As CoreValve has explained elsewhere, if the Court issues the full injunction requested by Edwards, then *Edwards II* would be moot because Edwards would not be entitled to any further relief. *Edwards II*, D.I. 15, at 7-8.

Section 271(f) applies only to "components" that are supplied from the U.S. in the form in which they will be "combined" to make the patented invention. *Microsoft Corp. v. AT & T Corp.* 550 U.S. 437, 449 (2007) (holding that software master discs did not qualify as "components" under § 271(f) because they were "uncombinable" with a computer until an additional copying step occurred abroad).

[8]

Moreover, these materials do not amount to a "substantial portion" of the invention under 35 U.S.C. § 271(f)(1). *See Rothschild v. Ford Motor Co.*, 2 F. Supp. 2d 941, 947 (E.D. Mich. 1998) (granting summary judgment for defendant that shipped three components from U.S. because they "contribute[d] minimally to the accused device and therefore § 271(f)(1) is wholly inapplicable"). The purported novelty of the invention, and the focus of infringement at trial, was on the Andersen stent and the CoreValve frame. D.I. 329 at 778:6-785:4; D.I. 331 at 1443:12-1446:19; D.I. 332 at 1612:23-1615:20.

D. I. 329 at 879:9-880:9.

[8] Even if the Court concluded that one of these materials was a "component," liability would still not attach because "§ 271(f)(1) cannot, as a matter of law, apply when only one component is 'supplied' abroad." *Ormco Corp. v. Align Tech., Inc.*, 609 F. Supp. 2d 1057, 1074 (C.D. Cal. 2009) (citing *Microsoft Corp.*, 550 U.S. at 458 n.18).

(f)(2).

Accordingly, there is no basis for liability under § 271(f)(2). *See Fieldturf, Inc. v. Sw. Recreational Indus., Inc.*, 235 F. Supp. 2d 708, 733 (E.D. Ky. 2002), *vacated in part on other grounds,* 357 F.3d 1266 (Fed. Cir. 2004) (to establish liability under § 271(f)(2), "plaintiff must have proof that the article has no use except in the patented invention").

V. CONCLUSION

Edwards' effort to obtain injunctive relief fails for one overarching reason: under any fact scenario for the future, an injunction will only cause harm (to patients, doctors and employees) and will not redress any injury to Edwards. Given that many who will bear the burden of this injunction may pay with their lives, Edwards motion should be denied.

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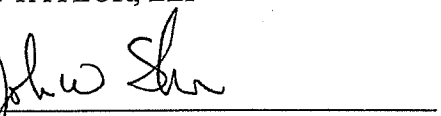

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CERTIFICATE OF SERVICE

I, Pilar G. Kraman, Esquire, hereby certify that on August 2, 2010, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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